



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Illicit Fentanyl Use and Urine
Drug Screening Practices in
a Domiciliary Residential
Rehabilitation Treatment
Program at the Bath VA
Medical Center
New York



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to address concerns regarding illicit fentanyl¹ use and urine drug screening (UDS) practices at the Domiciliary Residential Rehabilitation Treatment Program (DRRTP), Bath VA Medical Center (Facility), New York.

In early 2017, the Facility's police contacted the OIG Office of Investigations to report two non-fatal fentanyl overdoses. The OIG investigated and found that a DRRTP resident allegedly provided the fentanyl to other residents.² The investigation resulted in criminal legal proceedings against the resident who supplied the fentanyl. In May 2017, OIG investigators submitted a hotline referral to the OIG Office of Healthcare Inspections to address healthcare concerns related to fentanyl use and the Facility's UDS practices. The referral questioned if:

- The Facility could have done more to identify patients in the Enhanced Substance Abuse Treatment Program who were using illicit drugs, specifically fentanyl, through UDS. At least two residents experienced a non-fatal overdose of fentanyl, a drug which would not be detected in a routine UDS. There were three noted cases of illicit fentanyl use in the DRRTP.
- Veterans Health Administration (VHA) residential treatment programs, such as the DRRTP, should have more specific drug testing to identify illicit drugs like fentanyl that are trending in the community.

VHA does not require enhanced drug testing to identify fentanyl and other drugs not screened on routine UDS, and there was no identified cause to order an extended UDS for the DRRTP residents who later overdosed on fentanyl. In response to several incidents involving fentanyl abuse by residents in early 2017, Facility leaders took action to increase the identification of fentanyl use in DRRTP residents.

In March 2017, Facility leaders amended the UDS policy to include an extended panel UDS that included tests for fentanyl. The policy requires five percent of DRRTP residents to be randomly selected each day for an extended panel UDS. Facility leaders implemented additional actions including residents' UDS notification and same day testing, tracking of positive UDS results, ensuring naloxone rescue kits are visible and easily accessible to staff, clarifying staff responsibilities when a resident is found unresponsive, and using color-coded stickers on the outside of the residents' bedroom doors to identify residents who are at risk for illicit opioid use and/or at high risk for suicide.

¹ Fentanyl is a synthetic opioid that is legally used for treating severe pain.

² Residents are veterans who live in the DRRTP and participate in rehabilitation and treatment services.

The Facility's extended panel UDS that tests for fentanyl was processed by a non-VA laboratory with a turnaround time that compromised timeliness of clinical intervention and overdose prevention. OIG staff reviewed all fentanyl-positive UDS processed by a non-VA laboratory in fiscal year 2017 and the turnaround time for results ranged from 4.2 days to 13.2 days with an average time of 8.3 days. As of December 1, 2017, in an effort to improve timeliness, DRRTP staff receive a phone call from the non-VA laboratory relaying positive fentanyl UDS results.

The OIG determined that the Facility's fiscal year 2017 positive UDS tracking data was inaccurate. Facility staff recorded several UDS results incorrectly (two of the five tests recorded as positive by the Facility were negative), and confirmed positive UDS results were not included on the data tracking tool (three of the six tests). Staff stated that there was confusion interpreting the thresholds and some UDS results were recorded as positive when they were actually negative (false positive).

The OIG reviewed the electronic health records of 10 DRRTP residents to evaluate the Facility's fentanyl screening processes. All 10 residents had routine UDS during their admissions, as required by policy. Fentanyl was identified through an extended panel UDS in 7 of the 10 residents. The remaining three residents displayed physical symptoms and signs of opioid overdose and received medical treatment in a non-VA emergency department. Two of those three residents acknowledged illicit fentanyl use and the third resident reported heroin use. DRRTP staff provided appropriate follow-up and individualized care planning for nine of the 10 residents (one resident declined to participate in discharge planning) to address the illicit drug use. Treatment dispositions included residents' transfers to a higher level of care and residents' discharges to transitional housing, home, and/or outpatient treatment.

In March 2017, Facility leaders implemented a practice of placing color-coded stickers next to a resident's name on the outside of the resident's bedroom door. The goals of this practice were to allow Domiciliary Assistants to identify high-risk residents during room searches and bed checks and to provide DRRTP staff with more information when responding to emergent situations. OIG staff were told that differently colored stickers were used to identify residents with: opioid use prior to admission; a high-risk for suicide patient record flag; and both opioid use prior to admission and a high-risk for suicide patient record flag. Although this process was discussed in the Facility's Mental Health Council March 2017 meeting, key staff reported being unaware that the system was in effect. The Facility Suicide Prevention Coordinator and the Privacy Officer reported being unaware of the use of color-coded stickers for residents at high risk for suicide.³

At a minimum, Domiciliary Assistants conducted room searches weekly and locker searches monthly to identify prohibited items and illicit drugs. Although Facility leaders did not report

³ Facility leaders reported that managers communicated to the Privacy Officer, via email, the use of stickers to identify residents at high risk. However, the OIG team determined that the Privacy Officer was not aware that the stickers were being used to identify residents at high risk for suicide.

any related adverse incidents, OIG staff found that Domiciliary Assistants did not have sufficient personal protective equipment⁴ or training to safely and effectively conduct searches of residents' belongings.

VHA does not require treatment programs to routinely test for illicit drugs trending in the community, such as fentanyl. The American Society of Addiction Medicine⁵ and the Substance Abuse Mental Health Services Administration⁶ recommend routine testing based upon the types of drugs most abused in the region.⁷ VHA subject matter experts identified the benefit of including drugs prevalent in the specific region, such as fentanyl, in routine UDS. As of October 2017, a limited number of VHA facilities possess the additional laboratory equipment needed to conduct an extended panel UDS.

The OIG made eight recommendations related to drug screening guidelines, regional drug abuse identification, timely laboratory turnaround times and result notifications, positive UDS tracking and monitoring, UDS results interpretation training, color-coded sticker practices, and contraband search personal protective equipment and training.

Comments

The VHA Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans. (See Appendixes A–D, pages 29–36 for the comments.) Based on the information provided, the OIG considers recommendations 4 and 7 closed. For the remaining open recommendations, the OIG will follow up on the planned actions until they are completed.



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⁴ Personal Protective Equipment includes gowns, gloves, masks, and goggles worn to protect staff from injury and/or infection.

⁵ The American Society of Addiction Medicine is a professional medical society representing over 5,000 physicians, clinicians, and associated professionals in the field of addiction medicine.

⁶ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration is an agency that leads public health efforts to advance the behavioral health of the nation.

⁷ Jarvis M, Williams J, Hurford M, et al., Appropriate Use of Drug Testing in Clinical Addiction Medicine, *Journal of Addiction Medicine*. 11:1-56, May/June 2017; Substance Abuse and Mental Health Services Administration, Clinical Drug Testing in Primary Care. *Technical Assistance Publication (TAP)* 32. HHS Publication No. (SMA) 12-4668.

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Abbreviations

ASAM	American Society of Addiction Medicine
CDC	Centers for Disease Control and Prevention
DA	Domiciliary Assistants
DRRTP	Domiciliary Residential Rehabilitation Treatment Program
ED	emergency department
EHR	electronic health record
ESATP	Enhanced Substance Abuse Treatment Program
FY	fiscal year
IDT	interdisciplinary team
MH	Mental Health
OEND	Opioid Overdose Education and Naloxone Distribution
OIG	Office of Inspector General
PPE	personal protective equipment
RRTP	Residential Rehabilitation Treatment Program
SAMHSA	Substance Abuse Mental Health Services Administration
SUD	substance use disorder
TAT	turnaround time
UDS	urine drug screening
UNODC	United Nations Office on Drugs and Crime
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection of the Bath VA Medical Center (Facility) Domiciliary Residential Rehabilitation Treatment Program (DRRTP), New York, to review issues identified during an OIG investigation regarding illicit fentanyl use and the Facility's urine drug screening (UDS) practices.

Background

The Facility, part of Veterans Integrated Service Network (VISN) 2, is located in upstate New York and serves over 13,000 veterans from seven counties in New York and Pennsylvania. The Facility is a Complexity Level 2⁸ hospital that provides services including acute medicine, psychiatry, primary care, specialty care, and extended care. The Facility has 275 total operating beds, which include 170 DRRTP beds.

VA Domiciliary Care Program

Established in the 1860s to provide a home for disabled volunteer soldiers of the Civil War, the Domiciliary Care Program is the VA's oldest healthcare program. Over the years, the Domiciliary Care Program evolved into a clinical rehabilitation and treatment program for veterans with a variety of psychosocial and psychiatric care needs including homelessness, posttraumatic stress disorder, and substance use disorder (SUD). In 2005, the Veterans Health Administration (VHA) integrated the Domiciliary Care Program with the VHA Mental Health (MH) Residential Rehabilitation Treatment Program (RRTP) and as such, DRRTPs must adhere to MH RRTP requirements.⁹ DRRTPs utilize both peer and professional support to provide therapeutic, residential treatment to residents who are capable of self-care and do not require the level of bedside nursing care provided to inpatient psychiatric patients.

⁸ The VHA Facility Complexity Model has categorized medical facilities by Complexity Levels based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered to be the most administratively complex. Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing, <http://opes.vssc.med.va.gov/FacilityComplexityLevels/Pages/default.aspx>. (The website was accessed on October 12, 2017.)

⁹ VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010. This handbook was scheduled for recertification on or before the last working day of December 2015 and has not been recertified.

Facility DRRTP

The Facility's DRRTP provides structured, supportive care 24 hours per day, 7 days per week for up to 155 male and 15 female veterans (residents). Treatment is patient centered to meet the individual needs of each resident.¹⁰ Residents identify and address goals of rehabilitation, recovery, health maintenance, improved quality of life, and community integration. The resident and an assigned interdisciplinary team¹¹ (IDT) complete a comprehensive intake assessment, develop a treatment plan, and determine the resident's length of stay. If the IDT and the resident agree that the resident needs a more structured treatment program than that which is provided in the general DRRTP, the resident is admitted to the DRRTP's Enhanced Substance Abuse Treatment Program (ESATP). The ESATP is a program consisting of 24 beds within the Facility's DRRTP for residents who have had limited substance abuse treatment or the inability to maintain abstinence as an outpatient. The average length of stay in the ESATP is 28 days before a resident transfers into the general DRRTP. The ESATP prohibits off-campus passes, electronic devices, and resident access to vehicles. ESATP and DRRTP residents are required to abstain from contraband and illicit drugs and must cooperate with UDS.¹²

Opioid¹³ Overdose, Opioid Misuse, and Opioid Risk for Veterans

Approximately 115 people throughout the United States die each day from opioid overdose.¹⁴ The misuse of both prescription and illicit opioids continues to increase. In a November 2016 report, the Drug Enforcement Administration referred to prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the nation.¹⁵ Veterans have almost twice the risk

¹⁰ Within this context, a resident is defined as a veteran who lives in the DRRTP residential facility and participates in rehabilitation and treatment services.

¹¹ VHA Handbook 1162.02. "An interdisciplinary clinical team or teams of health care professionals and paraprofessionals with the training and expertise needed to provide interventions designed to benefit the Veteran, which may include the resident's family when included in the treatment plan."

¹² In this report, UDS is used to include urine drug screening(s), urine drug screens, and urine drug tests or testing.

¹³ Opioids are a class of drugs that include prescription pain relievers such as oxycodone, hydrocodone, morphine, codeine, and fentanyl, as well as the illicit drug heroin. In addition to pain relief, opioids can produce feelings of extreme well-being. With prolonged use, physical and/or psychological dependence can occur.

<https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused>. (The website was accessed on April 17, 2018.)

¹⁴ National Institute on Drug Abuse (NIDA), *Opioid Overdose Crisis*, Rev. March 2018.

<https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2017-01823-HI-0504/Work%20Papers/NIDA%20Data-%20March%202018%20opioid-overdose-c.pdf>. (The website was accessed on May 24, 2018.)

¹⁵ US Centers for Disease Control, (2016). *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*. <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>. (The website was accessed on December 11, 2017.)

for accidental overdose compared to the general United States population.¹⁶ “The potential overdose risks that veterans face as they readjust to civilian life are often rooted in their military experiences and the associated mental health and pain management challenges.”¹⁷ Opioids prescribed for pain management can pose a risk for dependence¹⁸ or overdose, especially if misuse¹⁹ occurs. Some veterans use illicitly received opioids for pain management or recreational use,²⁰ which also leads to dependence and/or overdose.

Fentanyl

Fentanyl²¹ is a synthetic opioid pain medication that produces an effect 50 to 100 times stronger than morphine. It is used in medical settings for anesthesia and is prescribed to treat patients with severe or chronic pain. Fentanyl is also used illicitly due to heroin-like effects, including reduced feelings of pain, increased euphoria, and relaxation.²² The drug is often mixed with heroin and/or cocaine to increase the potency, with or without the user’s knowledge.²³ Illegally manufactured fentanyl comes as a powder, on blotter paper, or as tablets that mimic other less potent drugs and can be swallowed, inhaled, injected, or absorbed through mucous membranes. Fentanyl injection use affects public health because it increases the risk for infections and infectious diseases. Fentanyl’s high potency and rapid onset are likely to increase the user’s risk for addiction, withdrawal symptoms, and overdose, especially if the user is unaware that the substance

¹⁶ Oliva, E, Christopher, M, et al., Opioid Overdose Education and Naloxone Distribution: Development of the Veterans Health Administration’s National Program. *Journal of the American Pharmacists Association*, Volume 57, Issue 2, Supplement, March–April 2017, Pages S168-S179.e4. <http://dx.doi.org/10.1016/j.japh.2017.01.022>. (The website was accessed on December 4, 2017.)

¹⁷ Bennett, A S, Elliott, L, et al., Opioid and Other Substance Misuse, Overdose Risk, and the Potential for Prevention Among a Sample of OEF/OIF Veterans in New York City. *Substance Use Misuse*, 2013 July: 48(10): 894–907. See page 2.

¹⁸ Dependence develops when neurons adapt to the repeated drug exposure and only function normally in the presence of the drug. When the drug is withdrawn, physiologic reactions can occur ranging from mild to life threatening. <https://www.drugabuse.gov/publications/teaching-packets/neurobiology-drug-addiction/section-iii-action-heroin-morphine/8-definition-dependence>. (The website was accessed on November 16, 2017.)

¹⁹ Misuse is the use of a drug for a purpose not consistent with legal or medical guidelines. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0015201>. (The website was accessed on November 16, 2017.)

²⁰ Recreational use of a drug occurs when a drug is used without medical justification for its psychoactive effects often in the belief that occasional use of such a substance is not habit-forming or addictive. <https://www.merriam-webster.com/dictionary/recreational%20drug>. (The website was accessed on November 16, 2017.)

²¹ Fentanyl is a drug that when sold illegally is known by names that include China White, Apache, Tango and Cash, TNT, Jackpot, Murder 8, Goodfella, and Dance Fever. <https://www.drugabuse.gov/nidamed-medical-health-professionals>. (The website was accessed on October 20, 2017.)

²² Heroin is an illegal, highly addictive drug processed from morphine. <https://www.drugabuse.gov/publications/research-reports/heroin/what-heroin>. (The website was accessed on November 7, 2017.)

²³ Fentanyl may be mixed with heroin and/or cocaine to increase its effects. <https://www.cdc.gov/drugoverdose/opioids/fentanyl.html>. (The website was accessed on October 30, 2017.)

consumed contained fentanyl. High dosages of fentanyl can also cause respiratory depression and death. See Figure 1 for an illustration of fentanyl's potency.



Figure 1. Size of a Lethal Fentanyl Dose as Compared to the Size of a Penny
Source: U.S. Drug Enforcement Administration²⁴

The Role of Fentanyl in the Opioid Crisis

In November 2017, the Centers for Disease Control and Prevention²⁵ (CDC) reported that overdose deaths involving fentanyl and fentanyl analogues²⁶ were contributing to the opioid crisis.²⁷ A CDC official told Congress that, “Drug overdoses in the United States have nearly tripled in the last 15 years.”²⁸ For many years, the increase in overdoses was attributed to prescription opioids; however, the recent increase in fatal overdoses was attributed to the use of heroin and synthetic opioids, specifically illegally manufactured fentanyl. According to the CDC, individuals who are incarcerated or in SUD or residential programs are at high-risk for overdose.

²⁴ Image of a lethal dose of fentanyl as compared to a penny. https://www.dea.gov/pr/multimedia-library/image-gallery/fentanyl/Faux_Fentynal_lethal_dose_005.jpg. (The website was accessed on November 16, 2017.)

²⁵ The CDC collaborates to create the expertise, information, and tools that people and communities need to protect their health through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

²⁶ Analogues are chemical compounds that are structurally similar to another but differ slightly in atomic composition. <https://www.merriam-webster.com/dictionary/analogue>. (The website was accessed on November 1, 2017.)

²⁷ O'Donnell, J.K., Halpin, J., Mattson, C., Goldberger, B., Gladden, R. M. (November 3, 2017). *Deaths Involving Fentanyl, Fentanyl Analogues, and U-47700 — 10 States, July–December 2016*. https://www.cdc.gov/mmwr/volumes/66/wr/mm6643e1.htm?s_cid=mm6643e1_w. (The website was accessed on April 14, 2018.)

²⁸ United States Congressional House Committee on Committee on Energy and Commerce Subcommittee on Oversight and Investigations. *The Next Wave of the Opioid Crisis. March 21, 2017*. 115th Congress. (statement of Dr. Debra Houry, Director of the National Center for Injury Prevention and Control at the CDC). <https://www.hhs.gov/about/agencies/asl/testimony/2017-03/fentanyl-next-wave-opioid-crisis.html?language=es>. (The website was accessed on October 20, 2017.)

Naloxone

Naloxone is a medication that can prevent injury and fatal outcomes by reversing overdose by opioids, including fentanyl. Naloxone comes in both intranasal and injectable forms. In 2013, the Substance Abuse Mental Health Services Administration (SAMHSA)²⁹ released an Opioid Overdose Prevention Toolkit that recommends strategies to healthcare providers, first responders, high-risk individuals, and family members to prevent and manage overdoses.³⁰ SAMHSA, CDC, and VHA recommend that overdose education and naloxone distribution are available to providers, patients, and families.

VA Opioid Overdose Education and Naloxone Distribution Program³¹

Veterans are more likely to suffer a fatal opioid overdose compared to non-veterans. To address opioid related mortality and harm, VHA developed the Opioid Overdose Education and Naloxone Distribution (OEND) program and implemented it at the facility level beginning in 2013.³² The VA OEND program models a community-based public health approach that includes overdose education and distribution of naloxone to veterans with opioid use disorders as well as those veterans prescribed opioid medication for pain.³³ Naloxone is available through the VA Pharmacy Benefits Management Services using the VHA National Formulary Process.³⁴ In an effort to prevent fatal and non-fatal opioid overdoses, the VHA Under Secretary for Health

²⁹ SAMHSA is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

³⁰ The SAMHSA Opioid Overdose Prevention Toolkit offers strategies to health care providers, communities, and local governments for developing practices and policies to help prevent opioid-related overdoses and deaths. Access reports for community members, prescribers, patients and families, and those recovering from opioid overdose: <https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA16-4742>. (The website was accessed on November 6, 2017.)

³¹ The VHA OEND mission is to reduce harm and risk of life-threatening opioid-related overdose and veteran deaths through education and training targeting opioid overdose prevention, opioid overdose rescue response, and issuing naloxone products. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/OEND_Fact_Sheet.pdf. (The website was accessed on November 13, 2017.)

³² Oliva, E, Christopher, M, et al., pages S168-S179.e4.

³³ Oliva, E, Christopher, M, et al., pages S168-S179.e4.

³⁴ The VA National Formulary Process is a list of products (drugs and supplies) generally covered under VA pharmacy benefits, and which must be available for prescription at all VA facilities. <https://www.pbm.va.gov/PBM/nationalformulary/VANationalFormularyFrequentlyAskedQuestions.pdf> (The website was accessed on March 1, 2018.)

issued a memorandum in 2014 recommending, “VA providers should consider providing OEND to Veterans who are at significant risk of opioid overdose.”³⁵

VHA Treatment for Opioid Misuse and Dependence

VHA facilities offer a continuum of care for opioid misuse and dependence that includes standard outpatient services, intensive outpatient programs, opioid substitution therapies³⁶ (opioid replacement therapies), residential rehabilitation, and acute hospital services.³⁷ Although not all VHA medical facilities directly provide the entire continuum of services to eligible veterans, all services must be available by referral to other VHA facilities, coordination with other VISNs, by sharing agreements,³⁸ contracts, or non-VA care.

Drug Testing

Individuals with substance use disorders, including opioid misuse and dependence, may not report their substance use behaviors accurately for a variety of reasons including a desire to continue substance use and/or to avoid legal, interpersonal, and/or employment consequences.³⁹ In substance use treatment, drug testing provides objective monitoring of treatment adherence and abstinence, and can assist providers in improving patient outcomes.⁴⁰ However, drug testing has some inherent limitations. Drug test results are dependent upon the type and amount of the drug used and when the individual last used the substance. An individual may have an SUD without necessarily having recent substance use; therefore, a negative result does not rule out a diagnosable SUD.⁴¹ In addition to drug testing, professional evaluation, patient self-report, and family input are critical in developing a comprehensive understanding of a patient’s substance use history and current situation.⁴²

³⁵ Under Secretary for Health’s Information Letter Implementation of Opioid Overdose Education and Naloxone Distribution (OEND) to Reduce Risk of Opioid-Related Death, May 13, 2014.

³⁶ Opioid substitution therapies are drug therapies used to treat opioid dependence and include methadone, heroin, buprenorphine, as well as naltrexone. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4171401/>. (The website was accessed on November 16, 2017.)

³⁷ VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD)*, March 7, 2012. This handbook was scheduled for recertification on or before the last working day of March 2017 and has not been recertified.

³⁸ VHA Handbook 1660.01, *Health Care Resources Sharing Authority – Selling*, October 11, 2007. Sharing agreements, or contracts, are entered into by VHA for the sale of healthcare resources and services. This handbook was scheduled for recertification on or before the last working day of October 2012 and has not been recertified.

³⁹ Jarvis, M, Williams, J, et al., Appropriate Use of Drug Testing in Clinical Addiction Medicine. *Journal of Addiction Medicine*, May/June 2017 – Volume 11, Issue 3, pages 163–173.

⁴⁰ Jarvis, M, Williams, J, et al.

⁴¹ Jarvis, M, Williams, J, et al.

⁴² Jarvis, M, Williams, J, et al.

*Drug Testing Methods*⁴³

Drug testing uses biological samples, such as urine, to detect when a specific drug and drug metabolites are present.⁴⁴ A urine sample is the most commonly used drug testing method in substance abuse treatment settings.

Screening and Confirmation

A positive UDS result indicates the presence of a targeted substance in the sample provided and that the concentration found was above a set targeted amount. A negative result indicates that a substance was undetected or the concentration was below a set targeted amount. General UDS laboratory practice is to first screen samples using a less expensive test, with a faster turnaround time (TAT) to rule out negative results and then to confirm potential positive results using a highly specific test. Immunoassays⁴⁵ are often used to screen samples, and chromatography,⁴⁶ combined with mass spectrometry,⁴⁷ is used to confirm positive test results. The most accurate drug testing method is chromatography/mass spectrometry. Although these techniques are more accurate than immunoassays, they are often more expensive and have longer TATs.

Drug Test Frequency

Because there is insufficient evidence that more frequent testing leads to decreased substance use, the American Society of Addiction Medicine (ASAM)⁴⁸ recommends that testing frequency

⁴³ Matrix is a term used to refer to the biological specimen type analyzed in a drug test. <https://www.ncsacw.samhsa.gov/files/DrugTestinginChildWelfare.pdf>. (The website was accessed on November 2, 2017.)

⁴⁴ Metabolites are substances that result from the way drugs are metabolized in the body. <http://www.merckmanuals.com/home/drugs/administration-and-kinetics-of-drugs/drug-metabolism>. (The website was accessed on November 2, 2017.)

⁴⁵ Immunoassay is a test used to detect the presence or quantity of a substance (such as a protein) based on its capacity to generate an immune response. <https://www.merriam-webster.com/dictionary/immunoassay>. (The website was accessed on November 2, 2017.)

⁴⁶ ASAM, *Appropriate Use of Drug Testing in Clinical Addiction Medicine*, April 5, 2017, page 9, Chromotography is a technique used to separate a sample into its component parts.

⁴⁷ ASAM, *Appropriate Use of Drug Testing in Clinical Addiction Medicine*, Mass spectrometry is a technique used to identify different substances within a sample.

⁴⁸ ASAM, founded in 1954, is a professional medical society representing over 5,000 physicians, clinicians and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction. <https://www.asam.org/about-us>. (The website was accessed on November 16, 2017.)

should be determined by the patient's severity of misuse or dependence and level of care.⁴⁹ To determine the frequency of testing, clinicians should also be aware of a test's detection capabilities, including the timeframe for detection.⁵⁰ ASAM recommends that a patient in early recovery be tested at least weekly and then at least monthly as the patient becomes more stable during recovery.

VHA Drug Testing Requirements

In 2013, the Assistant Deputy Under Secretary for Health for Clinical Operations issued guidelines for UDS as part of the provider's treatment planning to ensure patient safety for inpatient, residential, and outpatient SUD treatment programs.⁵¹ Further, facilities must have routine and confirmatory testing available for amphetamines, methamphetamines, benzodiazepines, cocaine, methadone, marijuana, oxycodone, opioids, and buprenorphine. Confirmatory testing should be performed to verify positive results or if the initial results are not consistent with self-reported use. Treatment program staff may use second tier testing,⁵² which tests for additional drugs, such as fentanyl.⁵³

VHA also requires that program managers ensure that relevant staff are sufficiently trained and have sufficient competencies to interpret UDS results and respond to positive results. VHA encourages staff to partner with laboratory personnel to share knowledge regarding drug testing.

Identifying Drug Use Trending in the Region

According to ASAM, a patient's routine drug test should be adjusted based on the patient's drug of choice, prescribed medications, and drugs commonly used in the patient's geographic location

⁴⁹ ASAM, *Appropriate Use of Drug Testing in Clinical Addiction Medicine*, April 5, 2017, page 24. Level of care refers to the points in a continuum of addiction treatment services. ASAM has established five main levels of care: Level 0.5 (Early intervention services); Level I (Outpatient services); Level II (Intensive outpatient/partial hospitalization services); Level III (Residential/Inpatient services) and Level IV (Medically management intensive inpatient services). [https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2). (The website was accessed on December 12, 2017.)

⁵⁰ Window of detection in urine may vary for drug and metabolite and detection depends on dose, frequency, and individual metabolism. <https://www.mayomedicallaboratories.com/test-info/drug-book/>. (The website was accessed on November 2, 2017.)

⁵¹ Assistant Deputy Under Secretary for Health for Clinical Operations, (September 5, 2013). Memorandum, Urine Toxicology Screening (Inpatient, Residential, and Outpatient Substance Abuse Disorder Treatment Programs).

⁵² Second tier testing is the traditional approach to drug testing that uses two levels of testing. The first tier targets large numbers of specimen samples. The second tier is generally performed using highly specific methods (gas chromatography or liquid chromatography with mass spectrometry) that confirm the testing results. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3550258/> (The website was accessed on December 14, 2017.)

⁵³ Assistant Deputy Under Secretary for Health for Clinical Operations, (September 5, 2013). Memorandum, Urine Toxicology Screening (Inpatient, Residential, and Outpatient Substance Abuse Disorder Treatment Programs).

and peer group. However, ASAM recognizes that the number of emerging drugs with abuse potential, especially synthetic formulas, will increase and therefore recommends that treatment programs update test panels regularly to address regional substance use trends.⁵⁴ To assist with the identification of widespread regional drug usage, SAMHSA compiles prevalence data on drug-related emergency department (ED) visits and deaths and provides this information to the public via the SAMHSA website.^{55, 56} In addition, substance use treatment program staff can be informed about regional substance use trends through the National Drug Early Warning System⁵⁷ or by contacting their Single State Agency.⁵⁸

Fentanyl Advisory Alert for the State of New York

In August 2016, the New York State Office of Alcoholism and Substance Abuse Services and the New York State Department of Health jointly issued an alert stating, "...New York State's heroin crisis is worsening with the presence of fentanyl." The Department of Health issued this advisory alert in response to a surge in illicit opioid overdoses driven mainly by heroin and illegally-made fentanyl. The Department of Health recommended that opioid users and responders learn the effects of fentanyl abuse and how to use naloxone and other measures to prevent an overdose.⁵⁹

⁵⁴ Hurford, M. et al. (2017). Appropriate Use of Drug Testing in Clinical Addiction Medicine, ASAM. *The Journal of Addiction Medicine*, Volume 11- Issue 3 - pg 7. [https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2). (The website was accessed on December 12, 2017.)

⁵⁵ SAMHSA's Drug Abuse Warning Network publishes prevalence data on drug-related ED visits and deaths; information is available at <https://www.samhsa.gov/data/>. (The website was accessed on April 16, 2018.)

⁵⁶ SAMHSA, (2012). *Clinical Drug Testing in Primary Care*, <https://store.samhsa.gov/shin/content/SMA12-4668/SMA12-4668.pdf>. Page 17. (The website was accessed on April 16, 2018.)

⁵⁷ National Drug Early Warning System (NDEWS), funded by the National Institute on Drug Abuse, monitors emerging drug use trends to enable health experts, researchers, and concerned citizens across the country to respond quickly to potential outbreaks of illicit drugs such as heroin and to identify increased use of designer synthetic compounds. <https://www.drugabuse.gov/related-topics/trends-statistics/national-drug-early-warning-system-ndews>. (The website was accessed on December 7, 2017.)

⁵⁸ Single State Agencies are the state government organizations responsible for planning, organizing, delivering, and monitoring critical substance use disorder services in each state. <https://store.samhsa.gov/shin/content/SMA15-4926/SMA15-4926.pdf>. (The website was accessed on November 2, 2017.)

⁵⁹ New York State Department of Health, 2016. *Fentanyl Alert*. https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/docs/fentanyl_alert.pdf (The website was accessed on October 30, 2017.) Other measures used to prevent overdoses include contacting 911 and learning more about the lethality of fentanyl and how it is sold.

Fentanyl Drug Testing and Extended Panels

VHA drug testing has traditionally conformed to SAMHSA guidelines.⁶⁰ Tests for opioid drugs do not identify all opioid drugs in the same manner or with the same specificity and thresholds. Fentanyl, in particular, shows essentially no reactivity to standard opioid immunoassays, such as the SAMHSA five-drug panel test,⁶¹ and it requires a separate drug test generally on an “extended panel.”⁶² The ability to create new fentanyl compounds by making small changes in chemical structure poses a growing challenge to fentanyl drug testing. According to the *United Nations Office on Drugs and Crime*⁶³ (*UNODC*) *Early Warning Advisory*,⁶⁴ 17 fentanyl analogues originated in countries in East Asia, Europe, and North America between 2012 and 2016.⁶⁵

Notification of Lab Results

VHA requires facility leaders to develop policies related to the communication of test results to patients.⁶⁶ The ordering provider must inform the patient of results requiring action within seven calendar days. Staff must document the communication in the patient’s electronic health record (EHR) including notification from the laboratory to the ordering provider as well as

⁶⁰ Milone, M. (2012) Laboratory Testing for Prescription Opioids. *Journal of Medical Toxicology*, 8(4): 408-416. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3550258/>. Page 3. (The website was accessed on December 13, 2017.)

⁶¹ SAMHSA Clinical Drug Testing in Primary Care, *Technical Assistance Publication Series 32*, (2012). The SAMHSA five-drug panel, also known as the SAMHSA 5, tests for the following drugs or their metabolites: amphetamines, cocaine metabolites, marijuana metabolites, opium metabolites and phencyclidine. <https://store.samhsa.gov/shin/content/SMA12-4668/SMA12-4668.pdf>. (The website was accessed on November 2, 2017.)

⁶² ASAM. *Appropriate Use of Drug Testing in Clinical Addiction Medicine* (2017). Extended panel expands the opiate drugs being tested for in the drug test. [https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2). (The website was accessed on December 12, 2017.)

⁶³ UNODC, *Fentanyl and its Analogues - 50 years On*. (2017). UNODC established in 1997 through a merger between the United Nations Drug Control Program and the Centre for International Crime Prevention operates in all regions of the world. UNODC is mandated to assist member states in their struggle against illicit drugs, crime, and terrorism. https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf. (The website was accessed on December 14, 2017.)

⁶⁴ EWA began in June 2013 as a response to the emergence of new psychoactive substances (NPS) at the global level. The EWA monitors, analyzes, and reports trends on NPS, as a basis for effective evidence-based policy responses and is a repository for information/data on these substances. <https://www.unodc.org/LSS/Page/About>. (The website was accessed on December 14, 2017.)

⁶⁵ UNODC, *Fentanyl and its Analogues - 50 years On*. (2017). https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf. (The website was accessed on November 1, 2017.)

⁶⁶ VHA Directive 1088, Communicating Test Results to Providers and Patients, October 7, 2015.

patient concerns.⁶⁷ Facility leaders must demonstrate periodic monitoring of test results communication to both providers and patients.⁶⁸

Facility DRRTP Policy and Procedures Regarding UDS Results

Prior to December 2017, notification of positive UDS results was sent to a designated printer located in the Facility's DRRTP. An electronically secure EHR alert was also sent. Nursing staff were responsible for checking the printer and communicating a positive test result to the resident's IDT via a secure electronic messaging system. The IDT would then meet with the resident to discuss the result, modify the treatment plan accordingly, ensure clinical intervention and follow-up of positive drug results, and document all actions in the EHR.⁶⁹

Personal Protective Equipment

The Occupational Safety and Health Administration⁷⁰ requires appropriate personal protective equipment (PPE)⁷¹ in healthcare settings.⁷² VHA requires a safe and healthy work environment in which employees "...receive training related to safe work practices, recognition of workplace hazards, and the proper selection, use and maintenance of PPE."⁷³ VHA Center for Engineering and Occupational Safety guidance states, "[a] properly executed hazard assessment is essential to an effective PPE program and includes the anticipation, identification, and evaluation of workplace hazards. Adequate assessment requires a team of experts to perform ongoing surveillance."⁷⁴

⁶⁷ VHA Directive 1088.

⁶⁸ VHA Directive 1088.

⁶⁹ MCM 300-003-031, Breath & Urine Testing Of Domiciliary Residential Rehabilitation And Treatment Program (DRRTP) Patients And Outpatients For Alcohol And Drug Analysis, March 2014. This policy was rescinded and replaced by MCM 300-003-031, March 2017. Both policies contain similar language relevant to this review.

⁷⁰ The Occupational Safety and Health Administration aims to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

⁷¹ PPE is equipment worn to protect staff from injury or infection, such as gowns, gloves, masks, and goggles. <https://www.osha.gov/Publications/osh3151.pdf>. (The website was accessed on November 7, 2017.)

⁷² Occupational Health and Safety Standards, Personal Protective Equipment, General Requirements. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=9777. (The website was accessed on December 13, 2017.); Occupational Safety and Health Administration, Personal Protective Equipment, OSHA Standards. <https://www.osha.gov/SLTC/personalprotectiveequipment/standards.html>. (The website was accessed on October 20, 2017.)

⁷³ VHA Directive 7701, Occupational Safety and Health, August 9, 2010. This directive was in effect at the time of OIG's review; it was rescinded and replaced by VHA Directive 7701, Comprehensive Occupational Safety and Health Program, May 5, 2017. Both directives contain the same or similar language relevant to this review.

⁷⁴ VHA Center for Engineering & Occupational Safety and Health (CEOSH), General Safety Guidebook, May 2017, page 100.

Federal Guidelines for Fentanyl Searches

The National Institute for Occupational Safety and Health under the CDC⁷⁵ issues specific recommendations for occupational exposure to fentanyl.⁷⁶ Employees conducting searches may be at risk for fentanyl exposure through inhalation, skin contact, and percutaneous exposure (needle stick). Exposure can potentially result in a variety of symptoms that include the rapid onset of life-threatening respiratory depression. The CDC recommends that employees use PPE when handling fentanyl and employers protect employees by identifying hazards and providing appropriate PPE.⁷⁷

Facility DRRTP Belongings and Room Searches

The DRRTP's Domiciliary Assistants (DA) conduct belongings and room searches⁷⁸ at random and pre-determined points in time, such as when a resident returns from pass, as required by VHA.⁷⁹ The purpose of the searches is to keep the DRRTP safe and drug free by identifying any hazardous items, such as weapons and illegal substances, and any items specifically prohibited by federal law⁸⁰ and Facility policy.⁸¹ DRRTP residents sign a document upon admission indicating their understanding of prohibited items, which includes searches.⁸²

⁷⁵ NIOSH is a research agency focused on the study of worker safety and health and empowering employers and workers to create safe and healthy workplaces.

⁷⁶ Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health (NIOSH), Fentanyl: Preventing Occupational Exposure to Emergency Responders. <https://www.cdc.gov/niosh/topics/fentanyl/risk.html>. (The website was accessed on October 20, 2017.)

⁷⁷ Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health (NIOSH), *Fentanyl: Preventing Occupational Exposure to Emergency Responders*.

⁷⁸ CFR 102-74.370 states, "Federal agencies may, at their discretion, inspect packages, briefcases and other containers in the immediate possession of visitors, employees or other persons arriving on, working at, visiting, or departing from Federal property. Federal agencies may conduct a full search of a person and the vehicle the person is driving or occupying upon his or her arrest." <https://www.gpo.gov/fdsys/pkg/CFR-2010-title41-vol3/xml/CFR-2010-title41-vol3-part102-id987-app-id1156.xml>. (The website was accessed on May 24, 2018.) The terms "search" and "inspection" are used interchangeably throughout VHA and local policies with regards to identifying contraband on federal property. For simplification, the term "search" is used in this report.

⁷⁹ MCM 300-003-18, *Domiciliary Residential Rehabilitation Treatment Program (DRRTP) Safety and Security*, June 2014. This Facility policy was in effect during the time of OIG's review; it was rescinded and replaced by MCM 300-003-18, *Domiciliary Residential Rehabilitation Treatment Program (DRRTP) Safety and Security*, June 2017.

⁸⁰ Code of Federal Regulations 1.218. <https://www.gpo.gov/fdsys/pkg/CFR-2011-title38-vol1/pdf/CFR-2011-title38-vol1-sec1-218.pdf>. (The website was accessed on November 16, 2017.)

⁸¹ MCM 300-003-18, *Domiciliary Residential Rehabilitation Treatment Program (DRRTP) Safety and Security*, June 2014. This Facility policy was in effect during the time of the OIG review; it was rescinded and replaced by MCM 300-003-18, *Domiciliary Residential Rehabilitation Treatment Program (DRRTP) Safety and Security*, June 2017.

⁸² MCM 300-003-18.

DRRTP staff document search findings in the EHR and notify VA police if they find a hazardous or illegal item. DAs dispose of items not retained by VA Police. If prohibited items are found, the resident's IDT convenes and initiates clinical intervention, such as patient education, counseling, or discharge from the program.⁸³

Prior OIG Reports

In a 2017 OIG report, *Comprehensive Healthcare Inspection Program Review of the Bath VA Medical Center Bath, New York* (Report No. 17-01752-32, December 7, 2017) the OIG identified DRRTP deficiencies in monthly self-inspections, weekly contraband inspections, two-hour rounds of public spaces, and daily resident room inspections. The OIG reviewed the Facility's self-inspection documentation from November 2016 through April 2017 and documentation of weekly contraband inspections conducted during April 2017. The OIG found process deficiencies and recommended monitoring of monthly self-inspections, weekly contraband inspections, every two-hour rounds of all public spaces, and daily resident room inspections. The recommendation remained open as of June 7, 2018.⁸⁴

Concerns

In early 2017, the Facility's police contacted the OIG Office of Investigations to report two non-fatal fentanyl overdoses. The OIG investigated and found that a DRRTP resident allegedly provided the fentanyl to other residents.⁸⁵ The investigation resulted in criminal legal proceedings against the resident who supplied the fentanyl. In May 2017, OIG investigators submitted a hotline referral to the OIG Office of Healthcare Inspections to address healthcare concerns related to fentanyl use and the Facility's UDS practices. The referral questioned if:

- The Facility could have done more to identify patients in the ESATP who were using illicit drugs, specifically fentanyl, through UDS. At least two residents experienced a non-fatal overdose of fentanyl, a drug which would not be detected in a routine UDS. There were three noted cases of illicit fentanyl use in the DRRTP.
- VHA residential treatment programs, such as the DRRTP, should have more specific drug testing to identify illicit drugs like fentanyl that are trending in the community.

⁸³ MCM 300-003-18.

⁸⁴ VA OIG Comprehensive Healthcare Inspection Program Review of the Bath VA Medical Center, Bath, New York, Report No. 17-01752-32, December 7, 2017.

⁸⁵ Residents are veterans who live in the DRRTP and participate in rehabilitation and treatment services.

Scope and Methodology

The OIG initiated the healthcare inspection on August 22, 2017.

The OIG interviewed Facility leaders and DRRTP managers and staff who were knowledgeable about the issues under review. OIG staff interviewed VHA subject matter experts from the VA Center of Excellence in Substance Abuse Treatment and Education; the VA Opioid Education and Naloxone Distribution program office; and the VA National Drug Testing Laboratory. OIG staff also interviewed a subject matter expert from the National Institutes of Health, National Institute on Drug Abuse.⁸⁶

OIG staff reviewed the Facility's policies and procedures for fentanyl related issues including overdoses, positive UDS results, and policy changes in fiscal year (FY) 2017. OIG staff reviewed relevant VHA and Facility policies and procedures related to the DRRTP and drug testing. OIG staff reviewed relevant meeting minutes, staff training records, VA issue briefs, and EHRs. OIG staff analyzed UDS results extracted from the VHA Corporate Data Warehouse (a centralized data repository that contains VHA clinical, administrative, and financial data). OIG staff also reviewed guidelines and recommendations from the CDC, SAMHSA, and ASAM.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

⁸⁶ The National Institute on Drug Abuse is a federal scientific research institute under the National Institutes of Health, U.S. Department of Health and Human Services. It is the largest supporter of the world's research on drug use and addiction. <https://www.drugabuse.gov/about-nida/frequently-asked-questions>. (The website was accessed on December 4, 2017.)

Case Summaries

Resident A

With a history of opioid dependence, Resident A entered the DRRTP ESATP (Day 1), completed the program, and transferred to a general DRRTP bed on Day 29. On Day 59, Resident A submitted a routine UDS with negative same day results documented. The next day, staff found Resident A in the bedroom unresponsive with labored breathing, successfully administered naloxone, and transferred Resident A to a community non-VA ED. Resident A returned to the DRRTP on Day 62 and reported that another resident provided Resident A with the fentanyl used on Day 59. The IDT allowed Resident A to complete four more days of treatment and then discharged to a non-VA shelter with outpatient follow-up on Day 66.

Resident B

After completing an inpatient opioid detoxification, Resident B entered the DRRTP ESATP (Day 1). On Day 15, Resident B submitted a random routine UDS and results were positive for opioids. On Day 19, DAs searched Resident B's possessions; no reason for the search was documented in the EHR. The search produced a baggie of unknown pills, a small orange "cap" with unidentified powder in it, a knife with a blade longer than three inches, straight razor blades, a needle, and a packaging wrapper for Suboxone®.⁸⁷ The DAs secured the prohibited items and turned them over to the VA police, per DRRTP policy.⁸⁸ Resident B submitted a random extended panel UDS that day; results received seven days later were positive for fentanyl. On Day 20, Resident B declined discharge planning and was discharged irregularly⁸⁹

Resident C

With a history of opioid dependence and recent opioid relapse, Resident C entered the DRRTP ESATP (Day 1). On Day 23, DAs conducted a random search of Resident C's room and confiscated energy drinks, cough drops, and an empty Suboxone® wrapper. Consequently, Resident C was required to submit an extended panel UDS. On Day 24, Resident C complained of nausea and vomiting and Facility staff transferred Resident C to a non-VA ED. Resident C returned to the DRRTP the following day and acknowledged use of fentanyl, heroin, and

⁸⁷ Suboxone® is a prescription medicine that contains the active ingredients buprenorphine and naloxone. It is used to treat adults who are dependent on opioids. <https://www.suboxone.com/Treatment/Suboxone-film>. (The website was accessed on November 17, 2017.)

⁸⁸ MCM 300-003-18, June 2014; MCM 300-003-18, June 2017.

⁸⁹ An "irregular discharge" occurs when a DRRTP resident leaves the program prior to completing the discharge process, which includes medical clearance from a DRRTP provider.

dextroamphetamine.⁹⁰ On Day 28, Resident C was discharged and chose to receive outpatient services rather than the IDT's recommended admission to the long-term residential program. Extended panel UDS results were received two days after Resident C's discharge and were positive for fentanyl.

Resident D

With a history of opioid dependence, Resident D entered the DRRTP ESATP (Day 1); and on Day 31, completed ESATP and transferred to the general DRRTP. On Day 35, Resident D submitted a routine UDS which was negative. On Day 38, staff found Resident D unresponsive on the bathroom floor with two syringes nearby. DAs successfully administered naloxone and transferred Resident D to a non-VA ED. Resident D returned to the DRRTP on Day 41, acknowledged fentanyl use, and expressed a desire to be discharged to an inpatient psychiatric unit. Following an evaluation by a provider at the Facility's Urgent Care Center, the Suicide Prevention Coordinator arranged a transfer to another VHA inpatient psychiatric unit for "continued [mood] stabilization."

Resident E

After completing inpatient detoxification for heroin use and opioid dependence, Resident E entered the DRRTP (Day 1). As a component of regular treatment, Resident E submitted a routine UDS on Days 38 and 39 with same day results positive for amphetamine and cocaine. On Day 39, Resident E presented to the case manager's office and reported a recent relapse on cocaine. Subsequent to the positive UDS and an IDT meeting, Resident E transferred to the ESATP for a higher level of recovery care. Resident E submitted four routine UDS the following week (Days 42, 43, 46 and 48) all of which had negative results. On Day 50, a nurse found Resident E in bed with labored breathing and transferred Resident E to a non-VA ED; Resident E was transferred back to the Facility's acute care unit for heroin detoxification. DRRTP staff documented that Resident E was discharged due to fentanyl use; however, OIG staff could not confirm that Resident E used fentanyl due to an absence of laboratory results from the non-VA ED in the VHA EHR. On Day 55, Resident E was irregularly discharged with plans to return home and attend outpatient care.

Resident F

After completing a 21-day inpatient substance abuse treatment program for opioid and benzodiazepine dependence at another VHA Facility, Resident F entered the DRRTP (Day 1).

⁹⁰ Dextroamphetamine is a stimulant that enhances the effects of certain chemicals in the brain. The dramatic increases in stimulant prescriptions over the last two decades have led to their greater availability and increased risk for diversion and abuse. <https://www.drugabuse.gov/publications/research-reports/prescription-drugs/stimulants/how-do-stimulants-affect-brain-body>. (The website was accessed on November 7, 2017.)

As a part of treatment, Resident F submitted numerous routine UDS with negative results until providing a random extended panel UDS on Day 46. On Day 48, Resident F self-reported a relapse on fentanyl the weekend prior and was discharged to a VA transitional housing program four days later (Day 52). The Facility received positive fentanyl results two days after discharge and eight days after the UDS sample was obtained.

Resident G

After completing detoxification for opioid dependence, Resident G entered the DRRTP ESATP (Day 1). As a part of routine treatment, Resident G submitted numerous UDS with negative results. On Day 23, Resident G submitted a random UDS. That evening, DAs conducted a search of Resident G's room and discovered a bag with white residue on it and the smell of bleach coming from the liquid inside the bag. That same evening, Resident G submitted an extended panel UDS. On Day 25, Resident G met with the IDT to discuss the items found by the DAs. During the meeting, a small package of powder and patch-like items fell from Resident G's pocket which was reported as fentanyl. On Day 29, Resident G was discharged to a non-VA shelter with scheduled outpatient follow-up care. The Facility received positive fentanyl results two days after Resident G's discharge.

Resident H

Resident H completed inpatient heroin detoxification and then entered the DRRTP ESATP (Day 1). On Day 32, Resident H completed the ESATP and transferred to the general DRRTP. On Day 70, Resident H informed a social worker of a heroin relapse the previous day and submitted an extended panel UDS. Resident H met with the IDT the following day to discuss the relapse and treatment plan modifications, which included initiating Suboxone® treatment. The results of the first extended panel UDS were received on Day 79 and were positive for fentanyl. Resident H continued to engage in treatment with a plan to discharge to outpatient MH and Suboxone® treatment. Resident H submitted an extended panel UDS on Day 102 and results were negative. Resident H was discharged on Day 115.

Resident I

With a history of opioid dependence, Resident I entered the DRRTP (Day 1). On Days 32 and 34, Resident I submitted extended panel UDS. Both tests were positive for fentanyl (results received on Day 39). On Day 36, Resident I described increasing stress and agitation with medications and DRRTP programming. Resident I communicated with members of the IDT and remained compliant with programming. On Day 39, after an initial report of increased stress, Resident I presented to the DRRTP Manager's office and discussed frustrations. The next morning, Resident I met with two IDT members to inform them that Resident I was leaving the DRRTP that day with plans to participate in outpatient treatment. On Day 41, Resident I left the

DRRTP before being evaluated and cleared by a medical professional; Resident I received an irregular discharge.

Resident J

After completing detoxification for heroin dependence, Resident J entered the DRRTP (Day 1). As a part of treatment Resident J submitted numerous routine UDS with negative results. On Day 31, Resident J submitted a random extended panel UDS that tested positive for fentanyl, as reported five days later (Day 36). On Day 37, Resident J acknowledged fentanyl use after a DRRTP social worker informed Resident J of the positive result. On Day 38, Resident J met with the IDT to discuss the plan to discharge due to fentanyl use and non-compliance with program policies. The DRRTP staff delayed the planned discharge until Day 42 so that Resident J could transfer directly into a parole approved housing program.

Inspection Results

Issue 1: Identification of DRRTP Residents Who Used Illicit Fentanyl

VHA does not require enhanced drug testing to identify fentanyl and other drugs not screened on routine UDS; and there was no identified cause to order an extended UDS for the DRRTP residents who later overdosed on fentanyl. In response to several incidents involving fentanyl abuse by residents in February 2017, Facility leaders took actions to increase the identification of fentanyl use in DRRTP residents.

In March 2017, Facility leaders amended the UDS policy to include an extended panel⁹¹ UDS that includes tests for fentanyl.⁹² Additionally, Facility leaders implemented⁹³

- Staff inform residents of same-day testing for UDS;
- Random extended panel testing for five percent of residents daily;
- A tracking mechanism for positive UDS results;
- Enhanced staff and resident awareness of and access to naloxone rescue kits;⁹⁴
- An “unresponsive resident” protocol; and
- The use of color-coded room door stickers to identify residents who were at risk for opioid use and/or at high-risk for suicide.

During the inspection, OIG staff also determined that DRRTP staff lacked PPE and sufficient training to perform required searches of resident belongings and bedrooms to identify fentanyl and other prohibited items.

⁹¹ ASAM. *Appropriate Use of Drug Testing in Clinical Addiction Medicine* (2017). Extended panel expands the opiate drugs being tested for in the drug test., [https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2). (The website was accessed on December 12, 2017.)

⁹² Facility policy Medical Center Memorandum (MCM) 300-003-031, Breath, Urine and Blood Testing of Domiciliary Residential Rehabilitation and Treatment Program (DRRTP) Patients and Outpatients for Alcohol and Drug Analysis, March 2017.

⁹³ MCM 300-003-031.

⁹⁴ All residents are informed about naloxone rescue kits and how to use them during program orientation. While doing room checks, DAs will observe for naloxone rescue kits, which are to be placed on the headboards of those residents with a history of opioid abuse. If naloxone rescue kits are not present, the DA will alert the resident’s IDT for follow up.

UDS

All residents of the DRRTP, including those in ESATP, undergo the same UDS processes. Upon admission, residents consent to an abstinence contract and receive the Facility's DRRTP Patient Handbook. Both documents identify UDS as a required component of treatment. Residents undergo a UDS at the time of admission, upon return from an authorized pass, routinely throughout treatment, and when there is reasonable suspicion that the resident may have used a prohibited substance. If a resident refuses to submit a UDS or the UDS is positive for illicit drugs, the resident is expected to meet with the IDT for counseling, treatment plan modifications, and/or program discharge.⁹⁵

Prior to March 2017, staff provided residents with advance notice (the day before) of their scheduled UDS appointment time via notices in residents' mailboxes. Since March 2017, residents are required to check the bulletin board at the entrance of their living area daily to see if they must submit a UDS. On the bulletin board, DAs post the mailbox numbers of the residents who are required to submit a UDS that day along with instructions to report to the nurse for testing between 10:30 a.m. and 12:30 p.m. DRRTP nurses obtain urine samples with direct observation of all residents at a minimum of once per week.⁹⁶

Extended Panel UDS

Consistent with the 2013 Assistant Deputy Under Secretary for Health for Clinical Operations guidelines, the Facility's routine UDS tests "...include[d] but [was] not limited to" methamphetamines, benzodiazepines, barbiturates, cocaine, methadone, marijuana, opioids, and phencyclidine.⁹⁷ In March 2017, Facility leaders amended their UDS policy as part of a response to fentanyl use by DRRTP residents. In addition to the routine UDS protocol, they implemented a daily requirement for an extended panel UDS to test for fentanyl, oxycodone, and buprenorphine for five percent of randomly selected residents.⁹⁸

Turnaround Time for Extended Panel UDS Results

The Facility laboratory is equipped to perform routine UDS with a TAT of one day. A non-VA laboratory processes all of DRRTP's extended panel UDS. The non-VA laboratory transports UDS specimens from the Facility on a daily basis Monday–Friday, excluding holidays. In FY 2017, hard copies of UDS results were automatically printed at a designated Facility DRRTP printer. However, the Nurse Manager stated that as of December 1, 2017, the process changed to

⁹⁵ MCM 300-003-031.

⁹⁶ MCM 300-003-031, "... Direct observation will be exercised by staff to guarantee the collection of a bona fide urine specimen. Patients will be afforded the maximum privacy consistent with VA patient's rights and regulations."

⁹⁷ MCM 300-003-031.

⁹⁸ MCM 300-003-031.

include a phone call from the laboratory relaying positive UDS results to the charge nurse. The Nurse Manager also reported that the addition of the phone call increased efficiency and timeliness so that clinical intervention to address positive UDS occurred as quickly as possible.

The non-VA laboratory was required to provide confirmatory tests for initial positive results for fentanyl within 10 days of sample receipt. OIG staff reviewed fentanyl-positive UDS that were processed by the non-VA laboratory in FY 2017 and TAT ranged from 4.2 to 13.2 days with an average TAT of 8.3 days. The processing TAT may have contributed to delays for the IDT's clinical intervention with residents who illicitly used fentanyl.

DRRTP Tracking of Residents' Fentanyl Use

Beginning in February 2017, DRRTP managers tracked the number of positive UDS, including those positive for fentanyl. OIG staff compared Facility data to an OIG independent data pull of DRRTP-ordered extended panel UDS. The Facility tracking data did not accurately reflect residents' positive fentanyl UDS results. The Nurse Manager stated that DRRTP managers track positive UDS results on a Facility spreadsheet; however, the spreadsheet did not include three of six residents who had positive UDS for fentanyl (identified in the OIG independent data pull) and also contained two entries erroneously identifying positive results. The OIG determined that staff reported results as positive even though the reported concentration did not meet the established threshold for a positive result.⁹⁹ The Facility laboratory manager stated that DRRTP staff sometimes misinterpreted UDS results and asked for help in "how to read it." Specifically, staff did not understand the thresholds and concluded that a UDS result was positive when it was in fact below the positive threshold (negative).

EHR Reviews of DRRTP Patients Who Used Fentanyl

The OIG reviewed 10 DRRTP residents' EHRs to evaluate the Facility's UDS processes for identification of fentanyl use. The 10 DRRTP residents included three residents (see Case Summaries, Residents A, B, and C) identified in the original allegation, two residents identified by Facility staff during interviews (see Case Summaries, Residents D and E), and five residents identified in the OIG review of FY 2017 DRRTP positive fentanyl tests (see Case Summaries, Residents F, G, H, I, and J).

All 10 residents had routine UDS during their DRRTP admission, as required by Facility policy. Fentanyl was identified through extended panel UDS for seven of the 10 residents. The remaining three residents (see Case Summaries, Residents A, D, and E) displayed physical

⁹⁹ Limit of quantitation describes the lowest concentration of a drug component that can reliably and consistently be detected and measured. Although amounts may be detected in concentrations that are below the limit of quantitation, these readings are considered unreliable. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2556583/>. (The website was accessed on December 4, 2017.)

symptoms and signs of opioid overdose and received medical treatment in a non-VA ED. Two of these three residents acknowledged fentanyl use; a third resident reported heroin use.

Nine of the 10 residents had EHR documentation of individualized care planning to address the illicit drug use. Care planning included residents' transfers to a higher level of care and discharges to outpatient treatment and/or programs such as transitional housing. Staff offered Resident B discharge planning; however, Resident B left the program prior to meeting with the IDT.

Additional Facility Actions

Naloxone Rescue Kits

Upon admission to the DRRTP, staff provided a "naloxone rescue kit" to residents with a history of opioid dependence. Residents were asked to hang the naloxone rescue kits on their bed headboards for visibility and easy access. DAs verified placement of the kits while conducting room checks and informed a resident's IDT if the kit was not present.

Unresponsive Resident Protocol

In March 2017, DRRTP managers developed an "algorithm" designed to outline specific steps and assigned staff roles if DRRTP staff encountered an unresponsive resident. DAs were informed of the algorithm, which was laminated and posted at each DRRTP desk, as well as included in the emergency rescue kit used by nursing staff.

Risk Identification System/Color-Coded Stickers

In March 2017, DRRTP managers implemented a practice of placing color-coded stickers next to a resident's name on the outside of the resident's bedroom door. The goals of this practice were to allow DAs to identify high-risk residents during room searches and bed checks and provide DRRTP staff with information when responding to emergent situations. Staff stated that differently colored stickers were used to identify residents with: opioid use prior to admission; a high-risk for suicide patient record flag; and both opioid use prior to admission and a high-risk for suicide patient record flag. All other residents received colored stickers that did not signify one of the given conditions.

Although the process was discussed in the MH Council March 2017 meeting, key staff reported being unaware that the system was in effect. Significantly, the Facility Suicide Prevention Coordinator and the Privacy Officer reported being unaware of the use of a color-coded sticker

for residents at high-risk for suicide.¹⁰⁰ While the DRRTP staff did not inform residents of the meaning of the color-coded stickers, this practice may have led to inadvertent disclosures. The DRRTP Manager stated that Facility leaders planned to re-evaluate the value of this system in early 2018.

Inadequate PPE and Staff Training for Searches

At a minimum, DAs conducted room searches weekly and locker searches monthly. Random and unannounced locker, room, backpack, and belongings searches occurred routinely for sanitation and safety purposes. Although Facility leaders did not report any related adverse incidents, the OIG found that DAs did not have sufficient PPE or training to safely conduct searches of residents' belongings or rooms.

Facility policy states, "PPE will be required and provided for employees to protect against the hazards identified in each area and based on the hazard assessment (formal or informal)."¹⁰¹ The OIG determined that the Facility lacked the necessary PPE for staff who conducted searches despite the potential dangers of fentanyl exposure. Facility leaders acknowledged the ongoing concern and provided documentation of multiple meetings and attempts to obtain appropriate PPE. Facility leaders stated that beginning November 3, 2017; staff were required to wear gowns and heavy gauge gloves when conducting searches. As of December 1, 2017, Facility leaders had approved the use of impermeable gowns, face masks, and nitro gloves, but continued to research options and vendors for disposable non-latex, puncture resistant gloves.

DRRTP staff stated that some DAs were unable to attend training for the identification of drugs and related paraphernalia due to their responsibilities on the unit while training sessions were in progress. Staff also stated that DAs did not receive sufficient training to ensure safe searching and proper identification of residents' prohibited items. The November 2017 Culture of Safety training for staff did not include training for safe searches, nor was there a reliable and accurate process for ensuring all staff attended the training that was provided. Without specialized training, illicit substances and related paraphernalia can be difficult to identify due to residents' packaging and concealment techniques.

¹⁰⁰ Facility leaders reported that managers communicated to the Privacy Officer, via email, the use of stickers to identify residents at "high risk." However, the OIG team found that the Privacy Officer was not aware that the stickers were being used to identify residents at high risk for suicide.

¹⁰¹ MCM 600-001-173, *Personal Protective Equipment*, September 2015.

Issue 2: VHA Practices in Response to Regional Illicit Drug Prevalence

VHA does not require treatment program staff to routinely test for drugs trending in the region, such as fentanyl. ASAM and SAMHSA recommend routine UDS panels based upon substances most abused in the region.¹⁰² VHA subject matter experts identified the benefit of routine UDS to include drugs prevalent in a Facility's specific region, such as fentanyl. However, as of October 2017, a limited number of VHA facilities possessed the laboratory equipment needed to conduct an enhanced or extended panel UDS.

Facility Responses to Drugs Trending in the Region

In March 2017, DRRTP leaders implemented an action plan that included increased testing of residents via extended panel UDS to test for drugs known to be used in the region, such as fentanyl. Additionally, DRRTP managers identified a plan to monitor trends in the region through DRRTP intake screenings, updates from VA police, and literature reviews to inform clinicians which drugs should be included on an extended panel screen. However, OIG staff did not find DRRTP managers' follow-up on this action. In September 2017, DRRTP managers distributed a written notice that alerted residents about a fentanyl analogue trending in the region and encouraged the residents to let staff know if they or another veteran needed assistance.¹⁰³

VHA National Programs and Tracking

The OIG spoke with national subject matter experts who discussed the challenges and possibilities of addressing the fentanyl crisis through VHA data collection and UDS. While VHA does track naloxone distribution, naloxone use, and opioid overdoses; reporting and tracking of illicit opioid overdoses is not mandatory and the data are not comprehensive. The VA National OEND Coordinator stated that tracking the administration of naloxone can help identify drug use trends within communities and provide opportunities for clinical intervention and overdose prevention. Specifically, the OEND Coordinator described value in tracking the distribution of naloxone, the use and/or refill of a naloxone prescription, as well as opioid related overdose events.

VHA's Director of the Center of Excellence in Substance Abuse Treatment and Education said that VHA leaders should implement fentanyl testing in treatment programs across the nation. While the Director acknowledged that the substances prevalent in a region vary by community,

¹⁰² Jarvis, M, Williams, J, et al.; Substance Abuse and Mental Health Services Administration, Clinical Drug Testing in Primary Care. *Technical Assistance Publication (TAP) 32*. HHS Publication No. (SMA) 12-4668.

¹⁰³ The Facility DRRTP released a written notice, called a "Buddy Check," to alert residents of a situation that may harm their health, or that of fellow residents. The notice regarding fentanyl included the statement: "Your safety is our #1 concern. If you or another Veteran that you know of needs assistance, please let us know immediately."

he reported that fentanyl has become so widespread that all treatment programs would benefit from including it in the UDS routine panel.

The Deputy Director of the National Institute on Drug Abuse, National Institutes of Health, stated that some derivatives of fentanyl may not show up on an extended UDS and that further testing would be required to identify unique fentanyl analogues. The inability to identify and test for all fentanyl analogues available in the community complicates the development of a comprehensive fentanyl testing program. The UDS must be modified based on the specific fentanyl analogue used by the resident and/or those currently prevalent in the community.

Further, VA's National Drug Testing Laboratory manager stated that laboratories need specialized equipment and expertise to test for fentanyl analogues. A limited number of VHA laboratories have the necessary equipment; however, even those facilities would need to adjust equipment and train staff to benefit from in-house testing. Testing equipment would need to be regularly adjusted to detect the fentanyl analogues identified in the community.

Conclusion

VHA does not require enhanced drug testing to identify fentanyl and other drugs not screened on routine UDS; and there was no identified cause to order an extended UDS for the DRRTP residents who later overdosed on fentanyl. In response to several incidents involving fentanyl use by residents in February 2017, Facility leaders took actions to increase the identification of fentanyl use amongst DRRTP residents.

In March 2017, Facility leaders amended their UDS policy to include an extended panel UDS, which tests for fentanyl. The policy requires five percent of DRRTP residents to be randomly selected each day for extended panel UDS. Facility leaders implemented additional actions including residents' UDS notification and testing on the same day; tracking of positive UDS results; ensuring naloxone rescue kits are visible and easily accessible; clarifying staff's responsibilities when a resident is found unresponsive; and using color-coded stickers to identify patients at risk for opioid use and/or at high-risk for suicide.

The Facility's extended panel UDS, that tests for fentanyl, was processed by a non-VA laboratory, with a TAT that may have compromised timeliness of clinical intervention and overdose prevention. OIG staff reviewed all fentanyl-positive UDS processed by the non-VA laboratory in FY 2017, and the TAT for results ranged from 4.2 days to 13.2 days with an average of 8.3 days. As of December 1, 2017, in an effort to improve timeliness, DRRTP staff receive a phone call from the non-VA laboratory relaying positive fentanyl UDS results.

The OIG determined that the Facility's positive UDS tracking data for FY 2017 was inaccurate. Specifically, staff recorded several UDS results incorrectly and confirmed positive UDS results were not included on the Facility's data tracking tool. Staff stated that there was confusion

interpreting the thresholds and some UDS results were recorded as positive when they were actually negative.

The OIG reviewed the EHRs of 10 DRRTP residents to evaluate the Facility's fentanyl screening processes. All 10 residents had routine UDS done during their admissions, as required by policy. Fentanyl was identified through extended panel UDS in seven of the 10 residents. The remaining three residents displayed physical symptoms and signs of opioid overdose and received medical treatment in a non-VA ED. Two of those three residents acknowledged fentanyl use and the third resident reported heroin use. DRRTP staff provided appropriate follow-up and individualized care planning for nine of the 10 residents (one resident declined to participate in discharge planning) to address the illicit drug use. Treatment dispositions included transferring residents to a higher level of care and/or discharge to transitional housing, home, and/or outpatient treatment.

In March 2017, Facility leaders implemented a process that placed color-coded stickers next to a resident's name on the outside of the resident's bedroom door. The goals of this process were to allow DAs to identify high-risk residents during room searches and bed checks and provide DRRTP staff with information when responding to emergent situations. OIG staff were told that differently colored stickers were used to identify residents with: opioid use prior to admission; a high-risk for suicide patient record flag; and both opioid use prior to admission and a high-risk for suicide patient record flag. Although the process was discussed in the MH Council March 2017 meeting, key staff reported being unaware that the system was in effect. The Facility Suicide Prevention Coordinator and the Privacy Officer also reported being unaware of DRRTP staff's use of color-coded stickers for residents at high-risk for suicide.¹⁰⁴

At a minimum, DAs conducted room searches weekly and locker searches monthly to identify prohibited items and illicit drugs. Although Facility leaders did not report any related adverse incidents, DAs did not have sufficient training or PPE to safely and effectively conduct searches of residents' belongings and bedrooms.

VHA does not require treatment programs to routinely test for drugs trending in the community and/or region, such as fentanyl. ASAM and SAMHSA recommend routine UDS panels based upon substances most abused in the region.¹⁰⁵ VHA subject matter experts identified the benefit of UDS that include drugs prevalent in the specific region, such as fentanyl. However, as of October 2017, a limited number of VHA facilities possessed the enhanced laboratory equipment needed to conduct an extended panel UDS.

The OIG made eight recommendations.

¹⁰⁴ Facility leaders reported that managers communicated to the Privacy Officer, via email, the use of stickers to identify residents at "high risk." However, the OIG team found that the Privacy Officer was not aware that the stickers were being used to identify residents at high risk for suicide.

¹⁰⁵ Jarvis, M, Williams, J, et al.

Recommendations 1–8

1. The Veterans Health Administration Under Secretary for Health ensures that drug screening guidelines for VA facilities are reviewed to determine if fentanyl should be included in routine urine drug screening, and takes appropriate action.
2. The Veterans Health Administration Office of Mental Health Services, Substance Use Disorders, Director considers developing and implementing a monitoring program to identify regional trends of drug abuse for facilities.
3. The Veterans Integrated Service Network 2 Director evaluates laboratory processes for fentanyl test results and takes appropriate action to ensure timely turnaround times and notification of results.
4. The Bath VA Medical Center Director ensures accurate tracking and monitoring of positive urine drug screening data.
5. The Bath VA Medical Center Director ensures that all Domiciliary Residential Rehabilitation Treatment Program clinical staff are trained on the interpretation of urine drug screening laboratory results.
6. The Bath VA Medical Center Director consults with appropriate personnel including ethics, legal counsel, privacy office, suicide prevention, and relevant Veterans Health Administration Program Office Directors to evaluate the risk identification/color-coded sticker system and ensure the practice is consistent with privacy standards and best practices.
7. The Bath VA Medical Center Director ensures that Domiciliary Residential Rehabilitation Treatment Program staff are provided personal protective equipment for use while conducting searches of resident belongings and rooms.
8. The Bath VA Medical Center Director ensures that Domiciliary Residential Rehabilitation Treatment Program staff are provided training on conducting safe and effective searches of resident rooms and belongings.

Appendix A: Under Secretary for Health Comments

Department of Veterans Affairs Memorandum

Date: July 10, 2018

From: Executive in Charge, Office of the Under Secretary for Health (10)^{106,107}

Subj: Healthcare Inspection—Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York

To: Director, Baltimore Office of Healthcare Inspections (54BA)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Review of Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York.
2. I concur with recommendations 1 and 2 and provide the attached action plan. The Veterans Integrated Service Network 2 Director is responsible for recommendation 3, and the Bath VA Medical Center Director is responsible for recommendations 4-8.
3. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

(Original signed by:)

Carolyn M. Clancy, M.D.

¹⁰⁶ The recommendations for the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

¹⁰⁷ The Executive in Charge provided a response for Recommendation 2, which the OIG addressed to the Director, VHA Office of Mental Health Services, Substance Abuse Disorders.

Veterans Health Administration

Action Plan

Draft OIG Report – Healthcare Inspection—Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York

Date of Draft Report: June 13, 2018

Recommendations/ Actions	Status	Target Completion Date
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Recommendation 1. The Veterans Health Administration Under Secretary for Health ensures that drug screening guidelines for VA facilities are reviewed to determine if fentanyl should be included in routine urine drug screening, and takes appropriate action.

Executive in Charge Comment: Concur

The Office of Mental Health and Suicide Prevention (10NC5) will convene a working group to review current guidance and determine feasibility of including fentanyl in routine drug screening at VA facilities. At the completion of this recommendation, a white paper with the working group recommendations will be provided to the Under Secretary for Health.

Status: In progress

Target Completion Date: October 31, 2018

Recommendation 2. The Veterans Health Administration Office of Mental Health Services, Substance Use Disorders, Director considers developing and implementing a monitoring program to identify regional trends of drug abuse for facilities.

Executive in Charge Comment: Concur

The National Program Director for Substance Use Disorders (SUD), in consultation with the Directors of the Centers for Excellence in Substance Addiction Treatment and Education and the Program Evaluation and Resource Center, will examine existing VHA decision-support tools and existing monitoring programs from the US Department of Health and Human Services (DHHS) and determine the feasibility of creating a VHA-specific drug use monitoring program or disseminating information about existing DHHS monitoring programs. The National Program Director for SUD will educate facility SUD leadership about the availability of resources on drug use trends (e.g., DHHS, Department of Justice) to track drug use trends in their regions through VHA National Addictions Conference Calls.

Status: In progress

Target Completion Date: January 31, 2019

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: July 2, 2018.

From: Director, New York/New Jersey VA Health Care Network (10N2)

Subj: Healthcare Inspection— Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York

To: Director, Baltimore Office of Healthcare Inspections (54BA)

Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed and concur with the findings and recommendations in the OIG report entitled, *Healthcare Inspection—Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York*.
2. If you have any questions, please contact the Deputy Quality Management Officer for VISN 2 at (716) 862-7479

(Original signed by:)

Joan E. McInerney, MD, MBA, MA, FACEP
VISN 2 Network Director

Comments to OIG's Report

Recommendation 3

The Veterans Integrated Service Network 2 Director evaluates laboratory processes for fentanyl test results and takes appropriate action to ensure timely turnaround times and notification of results.

Concur.

Target date for completion: November 30, 2018

Director Comments

The Veterans Integrated Service Network will conduct an evaluation of the Bath VAMC processes for fentanyl test results, turnaround times and notification of results. Appropriate action will be taken based on the process evaluation results. Results and actions, if any, will be followed at the VISN Quality, Safety and Value (QSV) Committee.

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Appendix C: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: July 2, 2018

From: Acting Medical Center Director, Bath VA Medical Center (528A6/00)

Subj: Healthcare Inspection—Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York.

To: Director, New York/New Jersey VA Health Care Network (10N2)

I have reviewed and concur with the findings and recommendations in the OIG report entitled, *Healthcare Inspection—Illicit Fentanyl Use and Urine Drug Screening Practices in a Domiciliary Residential Rehabilitation Treatment Program at the Bath VA Medical Center, New York*.

The medical center has completed several of the recommendations at the time of publication of the report. Action plans to address the remaining recommendations are in place.

I would like to thank the OIG Survey Team for their virtual review. The recommendations will strengthen both VHA and facility level processes to address the complex issues surrounding the care, treatment, and services provided to Veterans for opioid misuse and dependency.

Please contact me if you have additional questions or comments.

(Original signed by:)

Kenneth Piazza, MHSA, CPHQ

Acting Medical Center Director

Comments to OIG's Report

Recommendation 4

The Bath VA Medical Center Director ensures accurate tracking and monitoring of positive urine drug screening data.

Concur.

Completion Date: June 27, 2018

Director Comments

The process for accurate tracking and monitoring of positive drug screening data was developed and implemented during the course of this review. Tracking began on October 3, 2017 and continues; last date of entry was June 27, 2018 as evidenced in this report. The process includes receipt and timely communication of positive drug screening results from the laboratory to Domiciliary Residential Rehabilitation Treatment Program (DRRTP) nursing staff and subsequently to the assigned DRRTP treatment team members for intervention and treatment planning within one administrative business day of receipt of the positive results. The tracking tool includes all positive toxicology screens by date, name, substance confirmation request, results of confirmation testing and potential interfering substances such as medications prescribed. The timeliness of this process to include convening the interdisciplinary team within one business day is tracked through the Mental Health Performance Improvement Plan and reported quarterly to the facility Quality, Safety, Value (QSV) committee with 100% compliance noted for Q2 FY 18. A standard operating procedure was developed outlining the new process in January 2018. The Bath VA also added Fentanyl to the routine urine drug screening panel with the capacity to perform on-site testing. This has improved the turn-around time (TAT) to one hour which positively impacts staff's ability to monitor and provide timely patient interventions.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 5

The Bath VA Medical Center Director ensures that all Domiciliary Residential Rehabilitation Treatment Program clinical staff are trained on the interpretation of urine drug screening laboratory results.

Concur.

Target date for completion: September 30, 2018

Director Comments

The Bath Domiciliary Residential Rehabilitation Treatment Program (DRRTP) manager will schedule training through the Bath laboratory manager facilitated by Subject Matter Experts on interpretation of urine drug screening laboratory findings for DRRTP clinical staff. Training attendance logs will be maintained by the DRRTP manager.

Recommendation 6

The Bath VA Medical Center Director consults with appropriate personnel including ethics, legal counsel, privacy office, suicide prevention, and relevant Veterans Health Administration Program Office Directors to evaluate the risk identification/color-coded sticker system and ensure the practice is consistent with privacy standards and best practices.

Concur.

Target date for completion: September 30, 2018

Director Comments

The practice of identifying at risk Veterans admitted to the Bath Domiciliary Residential Rehabilitation Treatment Program (DRRTP) through a color-coded sticker system was implemented to improve staff's ability to respond appropriately and effectively to the needs of the Veteran population in our large residential program which includes 170 domiciliary beds. The color-coded system was reviewed by the Bath Privacy Officer who approved the practice, noting that it is similar to the process used in VA Community Living Centers to identify patient safety risks.

Additionally, this process was recognized as a strong practice by the Commission on Accreditation of Rehabilitation Facilities (CARF) during a recent accreditation site visit on May 14-16, 2018.

To ensure this practice is consistent with the appropriate standards, the facility will submit a local Integrated Ethics consultation requesting input from the National Ethics Program Office to evaluate the implications of implementing a high risk sticker designation process as it relates to other VHA Program Offices such as suicide prevention, privacy, ethics and legal counsel.

Recommendation 7

The Bath VA Medical Center Director ensures that Domiciliary Residential Rehabilitation Treatment Program staff are provided personal protective equipment for use while conducting searches of resident belongings and rooms.

Concur.

Target date for completion: June 7, 2018

Director Comments

A designated search room was established and equipped with Personal Protective Equipment (PPE) for use by the Domiciliary Assistants during searches which includes disposable puncture resistant gloves, gowns, head nets, feet covers, and face masks. Since the OIG virtual site visit, search carts with PPE were ordered, received and are utilized by staff to safely perform searches in Veteran rooms.

Pictures of both the search room and mobile cart are provided below.

Minutes from the Surge on Safety and Executive Committee of the Medical Staff (ECMS) outlines the history and commitment to developing PPE that provides the best protection for employees during searches. Despite extensive research through both local and national VA logistics departments as well as communications with community police agencies, mortuary services and on-line searches, puncture proof gloves with appropriate tactile discrimination features have not been located. At present we are providing the most protective products available to staff and this includes puncture resistant gloves, gowns, head nets, feet covers and face masks.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 8

The Bath VA Medical Center Director ensures that Domiciliary Residential Rehabilitation Treatment Program staff are provided training on conducting safe and effective searches of resident rooms and belongings.

Concur.

Target date for completion: September 30, 2018

Director Comments

Bath Domiciliary Residential Rehabilitation Treatment Program (DRRTP) staff currently receive training on conducting safe and effective searches of resident rooms and belongings during new employee orientation. This training is also reinforced at the annual Culture of Safety Stand Down. This training, provided by the Bath VA Police Department, includes hands-on simulation. Staff members are instructed in appropriate search techniques and are required to find hidden contraband throughout the room in mock-simulation exercises. A competency checklist outlining these training requirements was developed and will be completed within 30 days of new employee hires and annually thereafter. Staff will have completed competencies on file by the end of the fiscal year.

OIG Contact and Staff Acknowledgments

Contact For more information about this report, please contact the Office of Inspector General at (202) 461-4720.

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